

STATE OF \_\_\_\_\_  
DEPARTMENT OF \_\_\_\_\_  
CHAPTER 100A-1, ADMINISTRATIVE CODE  
CERTIFICATION OF ENVIRONMENTAL TESTING LABORATORIES

100A-1.005 Laboratory Certification Criteria.

(1) A laboratory certified by the Department of \_\_\_\_\_ pursuant to this rule must comply with the consensus standards adopted at the National Environmental Laboratory Accreditation Conference (NELAC). The NELAC Constitution, Bylaws, and Standards, revised as of July 2, 1998, are adopted by reference into this rule.

(2) STATE SUPPLEMENTAL CRITERIA: \_\_\_\_\_  
\_\_\_\_\_

Specific Authority: \_\_\_\_\_

Law Implemented: \_\_\_\_\_

History: New \_\_\_\_\_

100D-1.006 Certification Requirements.

(1) An application for certification shall be made in writing to the Department of \_\_\_\_\_ on Form \_\_\_\_\_, accompanied by the application fee listed in Rule 100A-1.017(2). Form \_\_\_\_\_, "Application for Accreditation of Environmental Testing Laboratories under NELAP," \_\_(revision date)\_\_ is also adopted by reference herein.

(2) Notwithstanding any other errors or omissions, an application is not completed until the laboratory has fulfilled all of the following requirements:

(a) The application reviewed by the Department of \_\_\_\_\_ includes the signed certification of compliance by laboratory management.

(b) Proficiency samples are successfully analyzed, if available, from a NELAP-approved proficiency test sample provider, for the requested analytes in the applicable sample matrix in two out of the latest three testing rounds attempted.

(c) A written Quality Manual has been prepared to include those NELAC-required elements relevant to the requested fields of testing (test methods and analytes).

(d) An on-site laboratory inspection has been conducted within the last two years for the test methods and analytes for which the laboratory is seeking certification, and any deficiencies noted have been corrected with a remedial action plan and estimated completion date acceptable to the department.

(e) Certification fees are paid as required in Rule 100A-1.017(3).

(f) The laboratory's Technical Director or Directors for the requested fields of testing were found to be qualified according to Section 4.1.1 of the NELAC Standards, referenced in Rule 100A-1.005(1).

(3) Applications for certification not completed within 2 years from the date received by the Department of \_\_\_\_\_ shall expire, and certification shall be denied.

Specific Authority: \_\_\_\_\_

Law Implemented: \_\_\_\_\_

History: New \_\_\_\_\_

100A-1.007 Certification of Out-of-State Laboratories.

(1) The Department of \_\_\_\_\_ shall certify an out-of-state laboratory to perform environmental sample analyses provided that the laboratory complies with all the requirements in this rule.

(2) An out-of-state laboratory shall be eligible for reciprocal certification to perform environmental sample analyses provided:

(a) The laboratory is certified by a state recognized as a NELAP Accrediting Authority for those fields of testing in which the laboratory is requesting certification pursuant to this rule.

(b) The laboratory submits to the Department of \_\_\_\_\_ an application on Form \_\_\_\_\_, which is adopted herein by reference, copies of the laboratory's three most recent proficiency test results, and its written Quality Manual.

(c) The laboratory submits to the Department of \_\_\_\_\_ a copy of its most recent (less than 2 years old) on-site inspection report from the Accrediting Authority or from the Accrediting Authority's delegated Assessor Body, together with a current copy of the laboratory's certification

and a listing of the categories, analytes, and test methods certified.

(3) If upon review of the documents listed in section (2) above the Department of \_\_\_\_\_ determines that the out-of-state certification program is equivalent to the requirements of this rule, the Department of \_\_\_\_\_ will not require an on-site survey by its inspectors and certification shall be granted after the assessed certification fees are paid.

(4) If upon review of the documents listed in section (2) above the Department of \_\_\_\_\_ is unable to determine that the out-of-state certification program is equivalent to the requirements of this rule, then the Department of \_\_\_\_\_ shall conduct an on-site inspection of the laboratory. The laboratory will be responsible for the cost of the on-site inspection. Alternatively, if the laboratory is located in a state that has a NELAP-approved accrediting authority, the Department shall contact that authority and request that its designated laboratory assessors conduct the on-site inspection.

(5) The Department of \_\_\_\_\_ shall grant certification if the results of the inspection verify compliance with this rule and after the invoiced certification fees and on-site inspection expenses are paid.

Specific Authority: \_\_\_\_\_

Law Implemented: \_\_\_\_\_

History: New \_\_\_\_\_

100A-1.008 Proficiency Testing Requirements.

(1) Laboratories shall bear the cost of any subscription to a proficiency testing program required by the Department of \_\_\_\_\_ for certification purposes. The Department of \_\_\_\_\_ shall not be charged a fee for the analysis of any performance evaluation samples.

(2) After the laboratory has submitted its application form or has become certified by the Department of \_\_\_\_\_, the laboratory must authorize the approved provider, prior to the testing round closing date of subsequent attempts, to submit the proficiency testing results to the Department of \_\_\_\_\_ concurrently with the submittal of these results to the laboratory. Otherwise, the Department of \_\_\_\_\_ shall refuse to consider the proficiency test results from that round for fulfilling the requirements of this rule.

(3) Proficiency test sample results shall be considered satisfactory when they are within the acceptance limits established by the approved proficiency test sample provider, according to one of the scoring options listed in Chapter 2, Appendix C of the NELAC Standards, which is referenced in Rule 100A-1.005(1).

Specific Authority: \_\_\_\_\_

Law Implemented: \_\_\_\_\_

History:                      New \_\_\_\_\_

100A-1.010 On-Site Laboratory Assessments.

(1) The laboratory shall ensure that its documented Quality System, analytical methods, quality control data, proficiency test data, laboratory standard operating procedures, and other records needed to verify compliance with this rule are available for review during the on-site laboratory inspection. The laboratory shall allow the Department's authorized personnel to examine records; observe the laboratory's procedures, facilities, and equipment; and interview staff as necessary to determine such compliance.

(2) The laboratory shall submit to the Department of \_\_\_\_\_ on Form \_\_\_\_\_ a Plan of Correction for each deficiency noted during the on-site evaluation. Form \_\_\_\_\_, "Statement of Deficiencies and Plan of Correction," \_\_(revision date)\_\_ is herein incorporated by reference.

(3) The Department of \_\_\_\_\_ is authorized to conduct on-site inspections of the laboratory at any time.

Specific Authority: \_\_\_\_\_

Law Implemented: \_\_\_\_\_

History:                      New \_\_\_\_\_

100A-1.011 Renewal of Annual Certification.

(1) The Department of \_\_\_\_\_ will renew a laboratory's certification after return of the renewal invoice on Form \_\_\_\_\_ and receipt of the renewal certification fee, provided the laboratory is maintaining compliance with this rule and attests to such compliance on Form \_\_\_\_\_. The Renewal Attestation of Compliance, Form \_\_\_\_\_, \_\_(revision date)\_\_, and Environmental Testing Laboratory Renewal Invoice, Form \_\_\_\_\_, \_\_(revision date)\_\_, are both herein adopted by reference.

(2) A laboratory's certification shall expire on July 1 of each calender year, unless its certification has been renewed.

(3) The Department of \_\_\_\_\_ will mail the renewal invoices and attestation forms at least 30 days prior to July 1. Failure to receive a renewal invoice does not exempt laboratories from paying the renewal certification fee.

(4) A laboratory whose certification has expired may reapply for certification in accordance with Rule 100A-1.006(1).

Specific Authority: \_\_\_\_\_

Law Implemented: \_\_\_\_\_

History: New \_\_\_\_\_

100A-1.012 Display of Certificate.

A current Certificate shall be displayed at all times in a prominent place in each certified laboratory where it may be

viewed by the public. Form \_\_\_\_\_, \_\_(revision date)\_\_, "NELAP Testing Laboratory Certificate," is adopted by reference herein.

Specific Authority: \_\_\_\_\_

Law Implemented: \_\_\_\_\_

History: New \_\_\_\_\_

#### 100A-1.013 Contractual Agreements, Records, and Reports.

(1) SPECIFIC STATE REPORTING REQUIREMENTS: \_\_\_\_\_

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(2) If a laboratory submits a sample to another laboratory facility for analysis, the first laboratory is responsible for determining that the contracted laboratory has been certified pursuant to this rule for the appropriate categories, test methods, and analytes for which it is being contracted to perform. Records at the laboratory shall include the sample analysis reports issued from each contracted laboratory.

Specific Authority: \_\_\_\_\_

Law Implemented: \_\_\_\_\_

History: New \_\_\_\_\_

#### 100A-1.014 Denial or Revocation of Certification.

(1) The Department of \_\_\_\_\_ is authorized to deny, suspend, limit, or revoke the certification of any

laboratory that does not comply with the requirements in the NELAC Standards, referenced in Rule 100A-1.005(1), and this rule.

(2) In determining the denial, revocation, suspension or limitation, the Department of \_\_\_\_\_ will consider such factors as the gravity of the offense, the danger to the public of the offense, the intent of the violation, the extent of the violation, and the proposed correction of the problem.

(3) The Department of \_\_\_\_\_ shall take agency action in accordance with \_\_(state regulations)\_\_\_ and shall afford a person whose substantial interests are affected an opportunity for an administrative hearing in accordance with \_\_(state regulations)\_\_\_.

(4) The Department of \_\_\_\_\_ is authorized to issue an emergency order immediately suspending the certification of a laboratory when it determines that any condition in the certified laboratory presents a clear and present danger to public health and safety.

Specific Authority: \_\_\_\_\_

Law Implemented: \_\_\_\_\_

History: New \_\_\_\_\_

100A-1.017 Fees.

(1) \_\_(State regulations)\_\_\_ authorizes the Department of \_\_\_\_\_ to charge and collect fees for the

evaluation and certification of laboratories pursuant to this rule.

(2) A nonrefundable application fee of \_\_\_\_\_ shall accompany each application. Such fee shall be assessed each subsequent application for additional analytes. The Department of \_\_\_\_\_ shall not retain this fee in circumstances where the application is not processed.

(3) In addition to the application processing fee, each laboratory shall pay to the Department of \_\_\_\_\_ the following fees for the initial certification and \_\_\_(time period)\_\_\_ renewal for each category of certification as follows:

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(4) The Department of \_\_\_\_\_ shall assess the expenses it incurs as a result of on-site inspection to the out-of-state laboratories, in addition to the application and certification fees in Subsections (2) and (3) of this section.

Specific Authority: \_\_\_\_\_

Law Implemented: \_\_\_\_\_

History: New \_\_\_\_\_